

# Veeva & U Clinical User Community

March 07, 2019





Jenn Embury

Manager, Clinical Customer Success



Anne Rudick-Lowe

R&D Customer Success Manager

# Agenda

Thursday, March 7th

**15:00 – 15:15**

## Welcome & Announcements

*Jenn Embury: Customer Success Manager, Veeva*

**15:15 – 16:00**

## Sponsor Oversight of CROs

*Jenn Embury: Customer Success Manager, Veeva*

**16:00 – 16:45**

## Measuring and Monitoring Quality Using Reports and Dashboards

*Anne Rudick-Lowe : Customer Success Manager, Veeva*

**16:45 – 17:00**

## Questions & Answers

*All*



# Community Meeting Objectives

Foster *customer success* by ...



Creating opportunities for **customer interaction**



Providing a forum to **share practices**



Promoting **product education**

Please use  
'Q&A' to ask a  
question



Audio Settings

Q&A

~~Chat~~

Raise Hand



Veeva R&D  
**SUMMIT**  
Europe

Register  
Now

**400+**  
attendees from  
life sciences

**90+**  
life science  
companies

Unify & Connect | 11 – 13 June 2019 | Barcelona, Spain

Join our European  
R&D Community



Share Best Practices



Develop New  
Industry Partnerships



Network with Peers



**REGISTER  
NOW**



Clinical  
Operations



Regulatory



Quality



Vault  
Platform

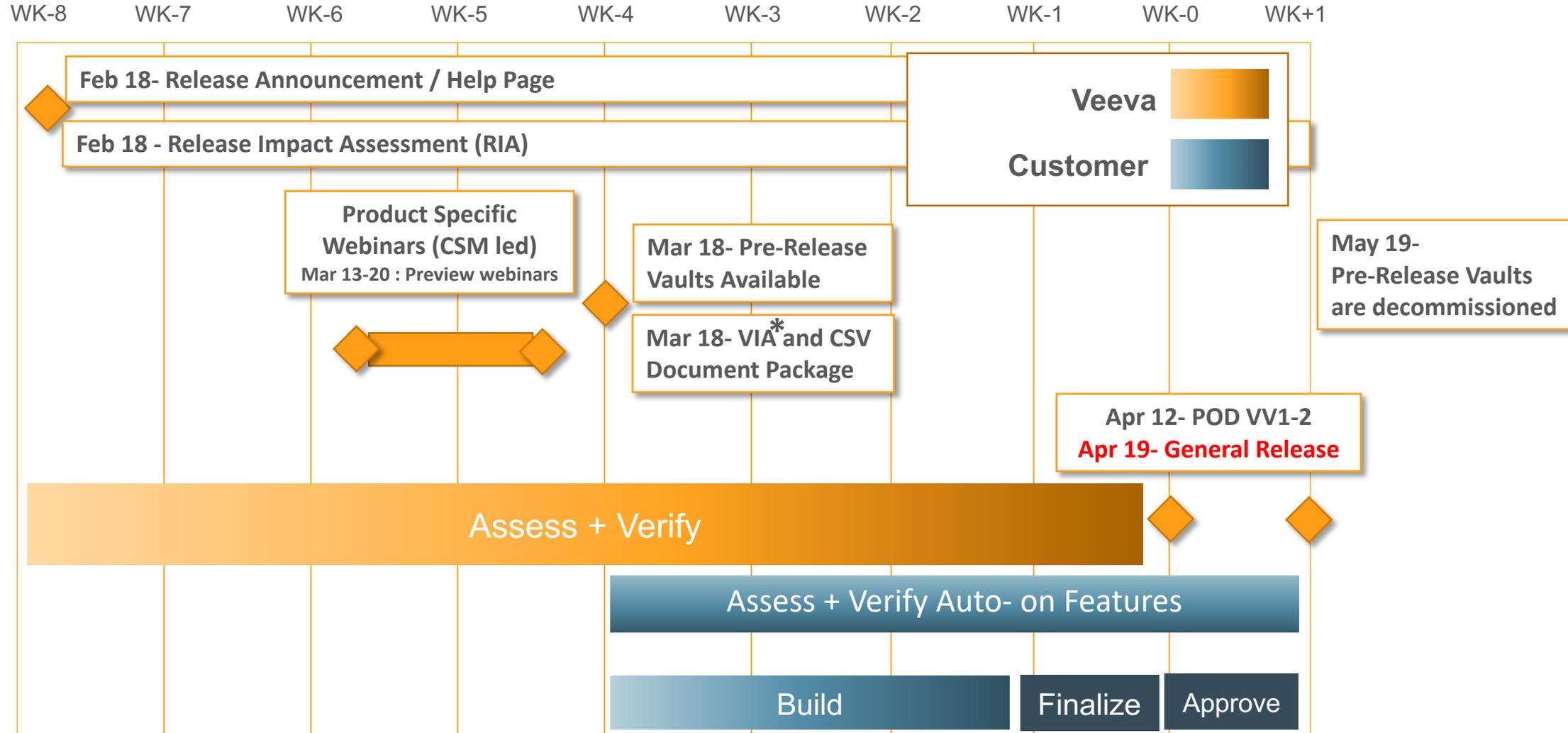
# Veeva & U

**Vault Clinical User Meeting - Remote**  
**7<sup>th</sup> March 2019**  
**15:00 – 17:00 CET**

**Vault Clinical User Meeting at Summit (Onsite Only)**  
**13<sup>th</sup> June 2019**  
**13:15 – 15:00 CET**



# 19R1 General Release (GR) Timing



\* Validation Impact Assessment



# Sponsor Oversight of CROs

EU Veeva & U Community Webinar

07 Mar 2019



# Table of Contents

**1**

**Sponsor Oversight - The Regulations**

**2**

**Sponsor Oversight of CROs- What does it mean?**

**3**

**Measuring and Monitoring Quality Using Reports and Dashboards**





# Regulations, Guidance, & Responsibility

# FDA and ICH E6

- FDA
  - 21 CFR 312.52 Transfer of Obligations
    - Allows FDA to take regulatory action against contracted party when inspectional findings at the contracted site show failure to comply with regulations
    - Does not relieve sponsor of their regulatory responsibilities
    - Sponsors should evaluate CRO compliance (e.g. Sponsor periodic review of monitoring reports, vendor performance, quality metrics, documented communication)
- ICH E6
  - Section 5.2.1 – The Sponsor always remains ultimately responsible for the quality and integrity of a study
  - Section 5.2.2 – Sponsor oversight is not just limited to the vendors they contract, but also includes the vendor's third parties
- References:
  - [FDA Guidance for Industry – Oversight of Clinical Investigations](#)
  - [21 CFR 312.52](#)
  - [FDA Compliance Program Guidance Manual](#)
  - [ICH E6 \(Section 5.2 Contract Research Organization\)](#)



# European Medicines Agency (EMA)

- Guidance on the Content, Management, and Archiving of the Clinical Trial Master file, *published 06 December 2018, effective 06 June 2019*
  - The sponsor may choose to outsource duties and functions of the sponsor to a CRO
  - The sponsor remains responsible for the trial and will need to maintain oversight. Therefore, access to the CRO maintained part of the sponsor TMF (e.g. by remote access to an eTMF) or at least regular access to relevant documents from it will be necessary to fulfil these responsibilities effectively



<https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/gcp-inspectors-working-group>

# MHRA – Good Clinical Practice Guide

- 1.1.3 The sponsor can formally delegate one or more of the functions of sponsorship
- 1.3.1 Regardless of the model used, the sponsor retains ultimate responsibility for the clinical trial.
- 1.3.1 All vendors must show due diligence when performing any functions they have been delegated...
- 10.2.6 The role of the vendor in the trial would be expected to be formally documented in an agreement between the sponsor and the vendor, outlining the functions transferred to the vendor
- 10.2.6 One such plan that may be considered is a TMF plan, particularly when the interactions between a vendor and sponsor are quite involved and complex and the agreement would not provide a sufficient level of detail of the practical working relationship
- 10.2.6 This plan (where used) must be filed in the TMF





# Oversight

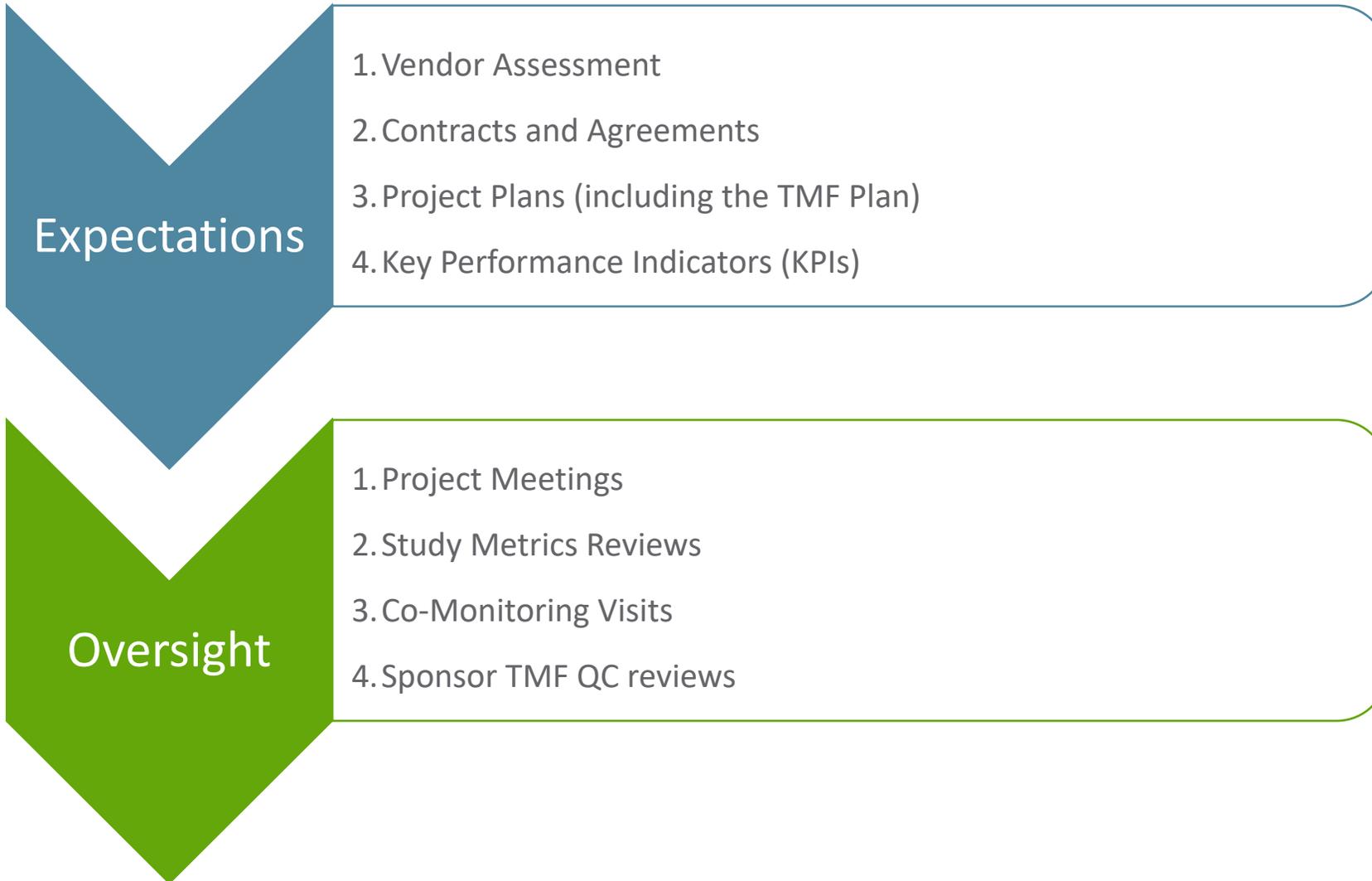
What does it mean?

# CRO Oversight

- Is my CRO doing what I hired it to do?
- Are they adhering to the TMF Plan?
- Are they meeting or exceeding expectations?



# CRO Oversight Activities & Documentation



# What is a TMF Plan?

- Describes the anticipated content of the Trial Master File (TMF)
- Is a living document that defines the process for creating, controlling, maintaining and archiving project-related document files



# What is in your TMF Plan?

- TMF Index/doc types
- Responsible Departments
- RACI
- TMF procedures/setup
- User access
- TMF archival and retention process
- Inspection process
- Certified copy definition
- Quality KPIs
- Timeliness definitions

- <https://tmfrefmodel.com/resources/>



TMF Plan  
Template



Inspection  
Readiness RACI



# Is my CRO doing what I hired it to do?

- No
  - Classifying incorrectly
  - Incomplete/wrong metadata
  - Uploading duplicate documents
  - Leaving documents unclassified in Inbox
- Yes
  - Providing high quality documents/few issues
  - Completing and uploading MVRs in alignment with monitoring plan
  - Contributing documents within xx days
  - Approving documents within xx days
  - Updating EDLs (if delegated)
  - Completing tasks on or before due date

Are they meeting or  
exceeding  
expectations?

- Apply a risk-based approach in the Sponsor's QC process
- Leverage Vault reports and dashboards to measure KPIs
- Use the TMF Homepage to identify trends





# Monitoring & Measuring Oversight

How Do We Demonstrate It?

# Monitoring & Measuring Oversight

- Metrics
  - What are you measuring today?
- Interim Quality Reviews
  - When are you performing reviews and what's included?



# Metrics: What to Measure?

- Quality Issue by Type
- Quantity of Documents
- Completeness
- Timeliness
- Comparing Sponsor to CRO Performance
- Comparing Multiple CROs
- Document Rejection Rate
- Upload Rate by Month by CRO
- Overdue Tasks, Workflows, and Document



# Interim Quality Reviews: Timing

- By milestones
- As needed (e.g. when one record is returned)







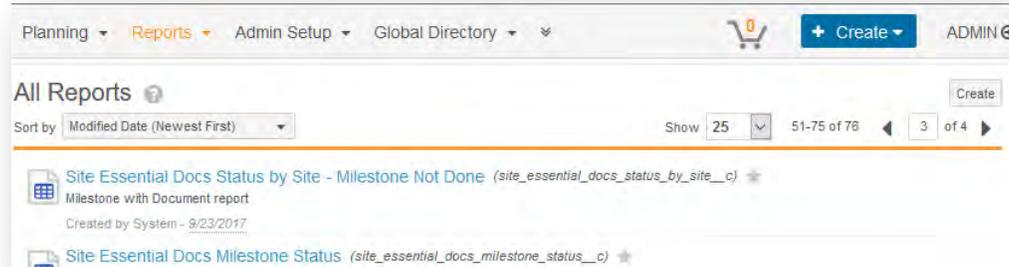
Questions



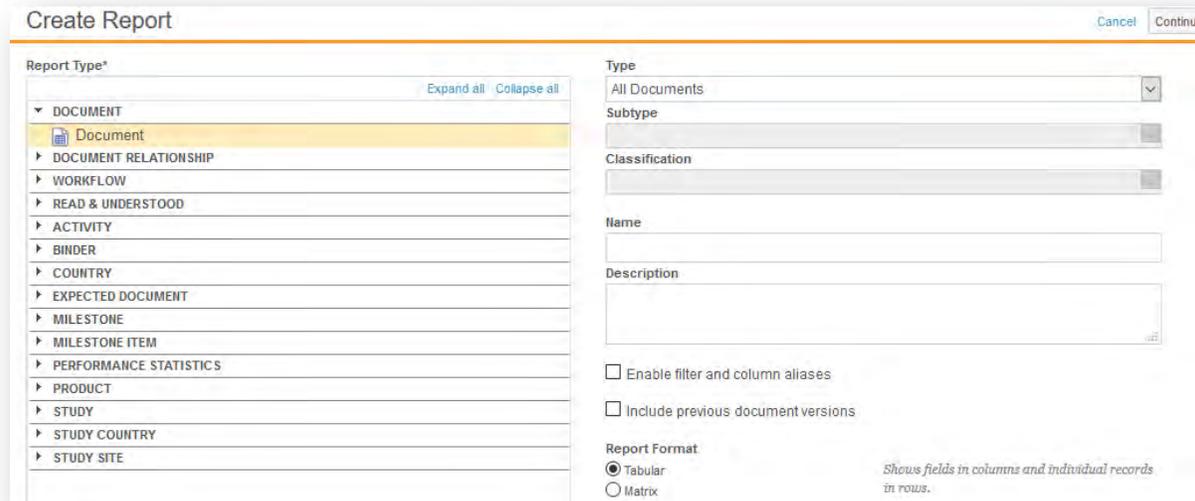
# Building Your Own Quality Reports and Dashboards

# Creating Reports

- To create a new Report, click the Create button on the Reports page



- When the Create Report screen opens, select the appropriate Report Type:



# Creating Reports

- Enter a Report Name and Description
- Select a Report Format:
  - **Tabular** – Fields are displayed in columns and document records are displayed on each row
  - **Matrix** – Fields are displayed in both columns and rows allowing summary calculations to be performed
- Optional Filters:
  - **Type** – limits documents and fields shown to the type, subtype, and/or classification chosen
    - Document reports only
  - **Enable filter and column aliases** – allows for renaming columns and filters to be better understood by users
  - **Include previous document versions** – by default reports will only show the latest version of a document; this will show all versions
    - Document reports only

# Creating Reports

- When the Report screen opens, specify any filters for the report by selecting appropriate properties, conditions and values

The screenshot displays the 'FILTERS (optional)' section of a report configuration tool. On the left, a tree view shows the hierarchy: 'Milestone > Milestone Type' is selected. Below it, under 'RELATIONSHIP CONSTRAINTS', are 'Milestones' and 'MILESTONE'. Under 'MILESTONE', several properties are listed: 'Actual Finish Date', 'Actual Start Date', 'Actual vs Planned Finish', 'Actual vs Planned Start', and 'Approval Comments'. A 'Milestones' tab is visible at the bottom left. The central area contains a dropdown menu with the value 'equals'. Below this, a text box contains the instruction 'they run this report.' followed by another dropdown menu with the value 'in'. On the right, a list of filter values is shown, with 'Study Financial Templates Completed' selected and highlighted in yellow. Other values include 'Pre Study Monitoring Visit', 'Pre Study Monitoring Visit(CTMS)', 'Protocol Approved', 'Ready to Enroll', 'Regulatory Activities Completed', and 'Site Essential Docs Completed'. Minus and plus icons are present next to the selected and some other values.

# Creating Reports

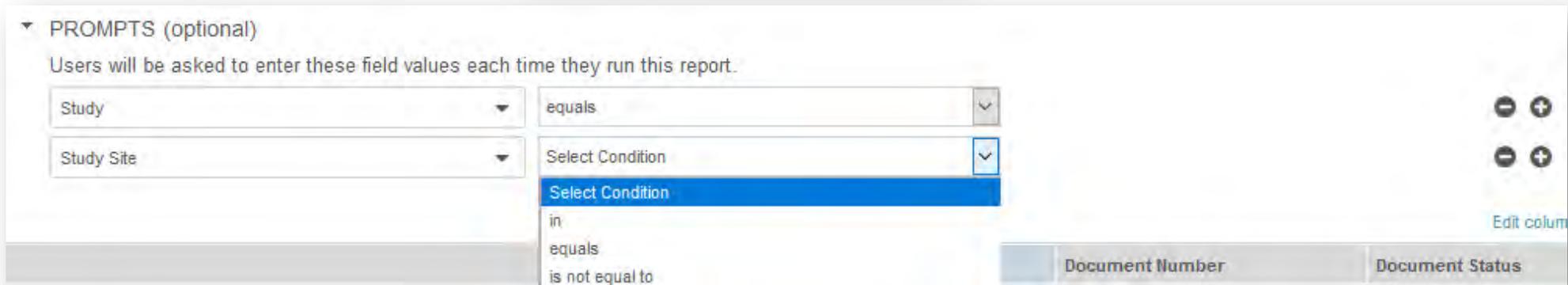
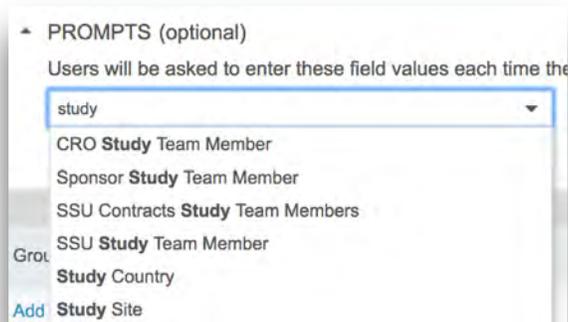
- Multiple filters can be applied by using the **+** button to add additional filters



- Clicking the **-** button can be used to remove an unnecessary filter

# Creating Reports

- If required, prompts can be added to further filter the report results by selecting the property and condition for the prompt
- A prompt appears as you run a report, requiring the user to enter certain filter criteria
  - Similar to filters, multiple prompts can be added (and subsequently removed) as needed



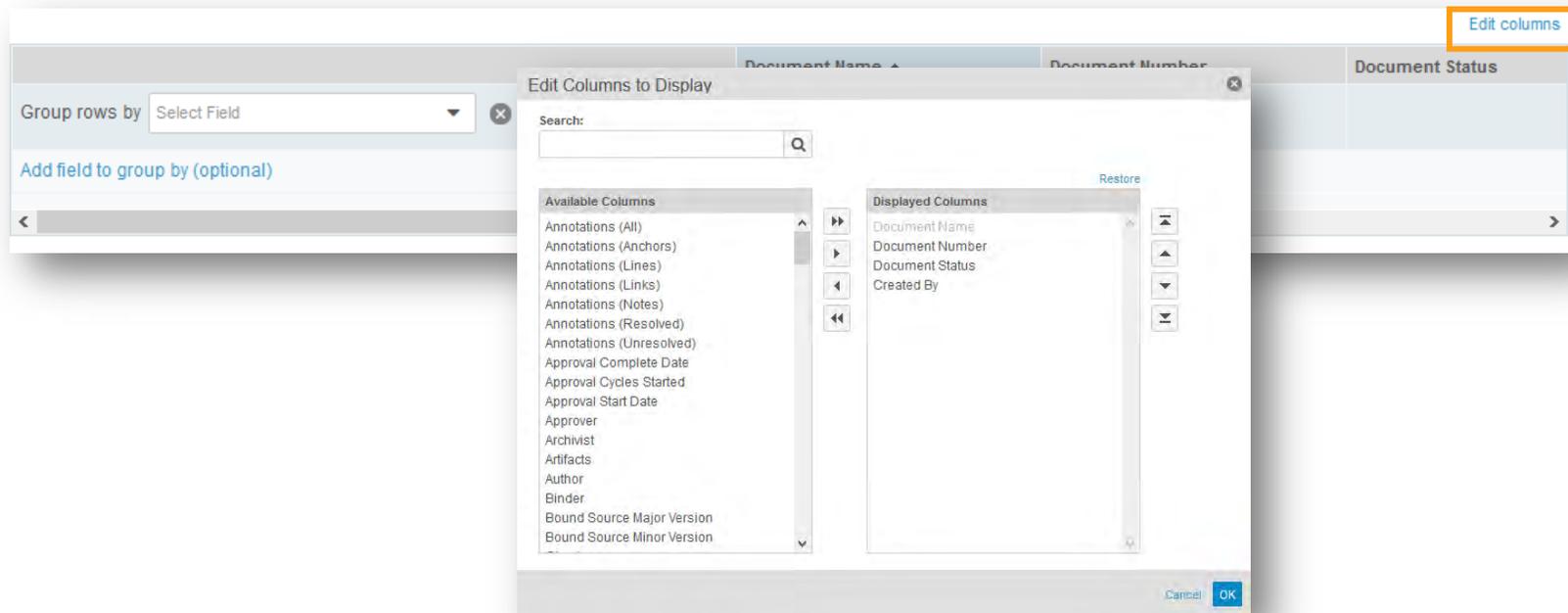
# Creating Reports

- Field groupings can also be applied to the report results
- Use groups to organize and sort your data by a specific field
  - A maximum of two grouping levels is currently permitted

The screenshot displays the Veeva Systems report creation interface. On the left, a 'Group rows by' dropdown menu is open, showing a list of fields including 'CRO Study Team Member', 'Sponsor Study Team Member', 'SSU Contracts Study Team Members', 'SSU Study Team Member', 'Study', 'Study Country', 'Study Site', 'Study Site Personnel', 'Study Startup Budget', and 'Study Startup CTA'. The main report configuration area shows a table with columns for 'Document Name', 'Document Number', and 'Document Status'. A 'Back to reports' button is visible at the top of the configuration area. Below the table, a 'Report' configuration section is open, showing a list of fields for the report, including 'Source Document Name', 'Source Number', 'Source Owner', 'Source Vault Name', 'Sponsor Employee', 'Sponsor Study Team Member', 'SSU Administrator', 'SSU Contracts Leads', 'SSU Contracts Study Team Members', 'SSU Lead', 'SSU QC', 'SSU Study Team Member', and 'Steady State Begin Date'. The 'Report' configuration section also includes a 'Group by' dropdown menu and a 'Sort by' dropdown menu.

# Creating Reports

- By clicking the Edit Column link, you can specify the columns to be displayed in the Report
- Select the columns from the Available Columns list and move them into the Displayed Columns list by clicking the right arrow to include them in the report
  - Columns in the Displayed Columns list can be reordered as needed by selecting a field and clicking the up or down arrows



# Creating Reports

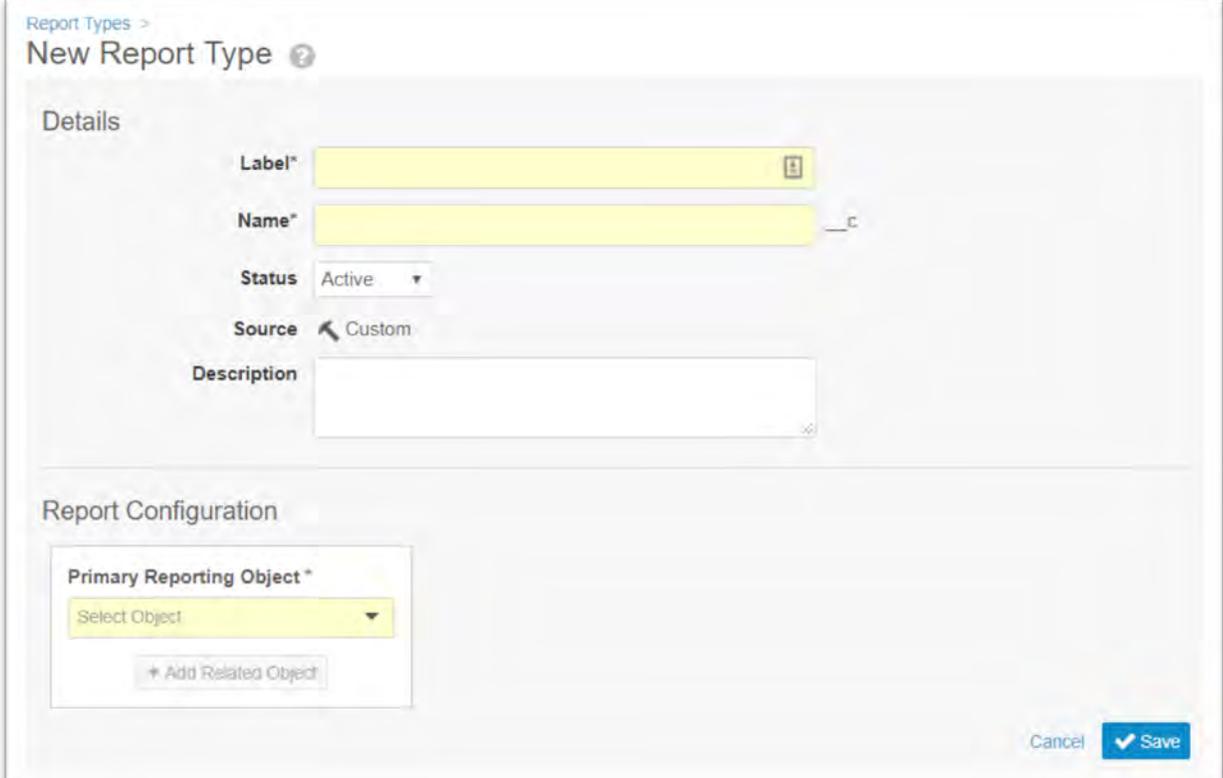
- Once the report filters, prompts, groupings and columns have been specified, you can perform the following actions
  - **Run:** Run will run the report without saving the specifics for future use
    - When the report is run, you have the options to continue editing, save or cancel the report. This is useful for testing the report as you configure it.
  - **Save:** Save will save the report so that it is available to be run in the future
  - **Cancel:** Cancel will return you to the Reports list without saving or running the report

The screenshot shows a report configuration interface. At the top right, there are three buttons: 'Cancel', 'Run', and 'Save'. The 'Run' button is highlighted with an orange box. Below the buttons, the report title is 'Expected Documents with Documents - Study Countries'. The report type is 'Expected Document with Matched Document'. There are two sections: 'CONDITIONAL FIELDS' and 'FILTERS (optional)'. Under 'FILTERS (optional)', there are two filter rules. The first rule is 'Expected Document > Requiredness' with a value of 'in' and a list of values 'Required' and 'Pending Decision'. The second rule is 'Expected Document > Level' with a value of 'in' and a list of values 'Country'. Each rule has a minus sign and a plus sign button to its right.

# Reports

## Creating New Report Types

- If a report type isn't available, Admins can create new report types for existing objects
- Admin > Configuration > Report Setup > Report Types
- Select 
- Label the new Report Type
- Select the Reporting Objects



The screenshot shows the 'New Report Type' configuration form. The form is divided into two main sections: 'Details' and 'Report Configuration'. In the 'Details' section, there are fields for 'Label\*', 'Name\*', 'Status' (set to 'Active'), 'Source' (set to 'Custom'), and 'Description'. In the 'Report Configuration' section, there is a 'Primary Reporting Object\*' dropdown menu with 'Select Object' as the current selection, and an '+ Add Related Object' button. At the bottom right, there are 'Cancel' and 'Save' buttons.

# How to Create a Formula Field

- **Admin > Configuration > Document Fields**
  - Click on document type where you would like to define this formula field
- Click **Add...** and select **New Field**.
- Select **Formula** as the field type.
- Enter a label for the field. This label will appear when using the field as a report column, filter, or group by field.
- Set the **Status**. If *Active*, the field will be available as soon as you save. If *Inactive*, you'll have to change the status before the field is available.
- Choose the number of **Decimal Places** that Vault should round to for the field's final value.



# How to Create a Formula Field

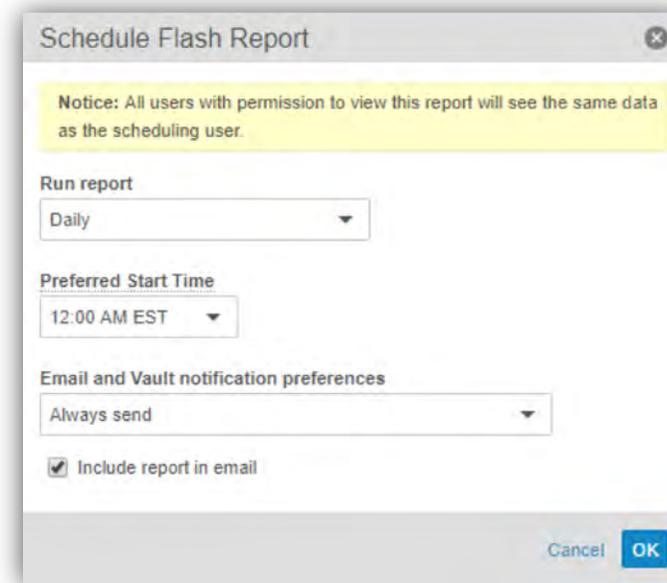
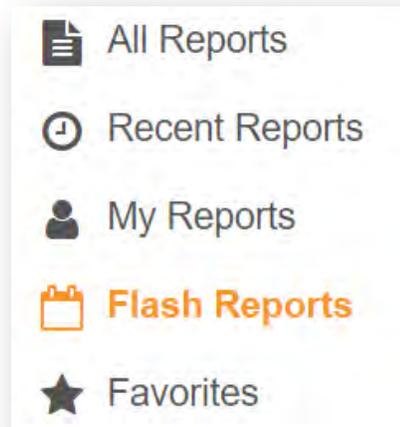
- Use items from the **Fields** and **Functions** panels, plus math operators as needed, to create an expression in the **Formula** field. To move an item from these panels to the **Formula** field, highlight it and click the arrow icon. The **Formula** field functions like a basic text editor. Learn more about available functions and operators in the [Vault Formula Reference Guide](#).
- Click **Validate**. Vault will let you know if your expression is valid.
- Choose a **Field Value Handling** option. **Treat blank values as zeros** allows Vault to perform calculations even if one or more values is blank. **Treat blank values as blanks** returns a null or invalid result if the formula contains blank values. Learn more about [Blank Value Handling](#).
- Optional: Enter text for **Help Content**. This text appears when a user hovers over the document field name.
- Click **Save**.



# Reports

## Flash Reports

- Schedule reports on a daily, weekly, or monthly frequency
  - Can distribute via email to users with the Editor or Viewer role
  - Recipients receive a link with instant access to the most recent cached report results in Vault without needing to rerun the report
  - A preview of the report can be included in the Flash Report email
  - **Recipients do not require view permissions on underlying object records or documents to view the cached flash report results**
  - Cannot be refreshed
  - Not available for reports with prompts



A dialog box titled 'Schedule Flash Report' with a close button in the top right. It contains a yellow notice: 'Notice: All users with permission to view this report will see the same data as the scheduling user.' Below the notice are three sections: 'Run report' with a dropdown menu set to 'Daily'; 'Preferred Start Time' with a dropdown menu set to '12:00 AM EST'; and 'Email and Vault notification preferences' with a dropdown menu set to 'Always send'. At the bottom, there is a checked checkbox for 'Include report in email' and two buttons: 'Cancel' and 'OK'.

# Editing Reports

- When you select to edit the report, the filters, grouping and prompts previously specified will be displayed and available for modification

IP Release Completeness - By Site

Report Type: Milestones and Expected Documents

CONDITIONAL FIELDS

FILTERS (optional)

- Milestone > Milestone Type equals IP Release Approved
- Expected Document > Requiredness equals Required
- Milestone > Actual Finish Date is blank

PROMPTS (optional)

Users will be asked to enter these field values each time they run this report.

- Milestone > Study equals

Milestone Item

Group rows by: Milestone > Study Site

Sort groups by: Min of Actual Finish Date (Oldest First)

Milestone Item	Planned Finish Date	Actual Finish Date	Expected Document
			Expected Document
			Document Type
			Document Subtype
			Document Classification
			# Expected

Expected Document > Completeness

Completeness (A-Z)

# Editing Reports

- After saving the report, you will be able to run it, edit it and perform other actions
- When the report is run, the real-time results will be displayed with the options to
  - **Refresh:** Rerun the report with updated results
  - **Edit:** Make modifications to the filters, prompts, and groups of the report
  - From the Actions Menu, you have the options to:
    - Share the report with other users
    - Export the report results to CSV, Excel, or PDF
    - Make a copy of the report
    - Delete the Report

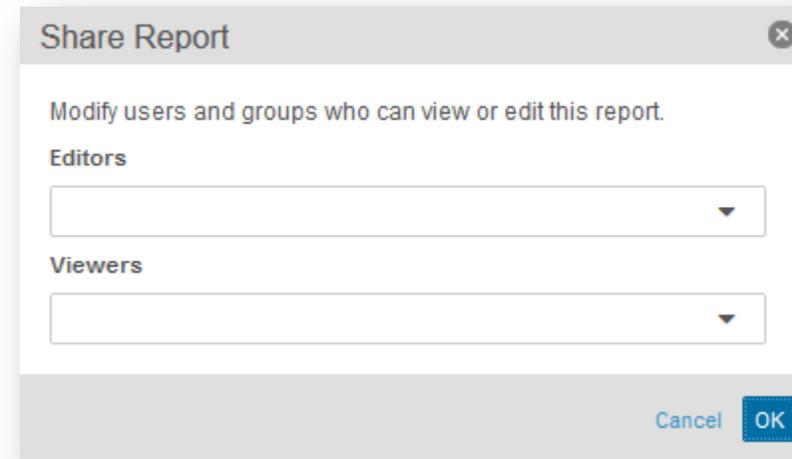
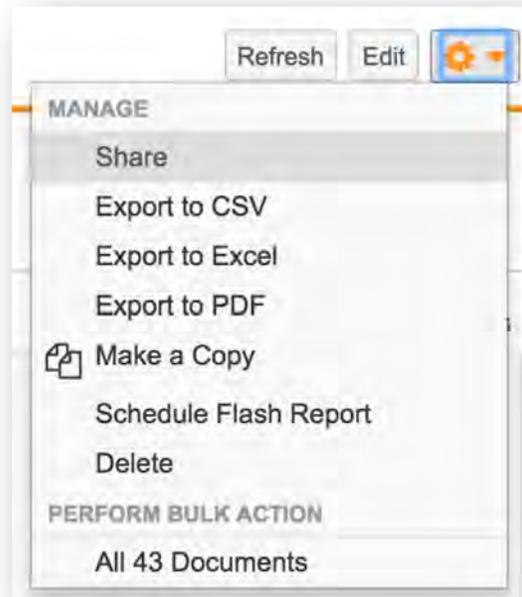
The screenshot shows a report titled "Site Essential Docs In House Cycle Times By Country" with a star icon. At the top right, there are buttons for "Refresh", "Edit", and a gear icon. Below the title, it says "Report Type Milestone with Document". There is a "FILTERS (2)" section with a plus icon and a pencil icon. Below that, there are "Expand all" and "Collapse all" links. The main data area is a table with two sections: "Milestone (5)" and "Document (13)". The "Milestone" section has columns for "Milestone", "Baseline Finish Date", "Planned Finish Date", and "Actual Finish Date". The "Document" section has columns for "Document Name", "Classification", "Document Status", and "Days at Site". A "MANAGE" menu is open over the "Days at Site" column, listing options: "Share", "Export to CSV", "Export to Excel", "Export to PDF", "Make a Copy", "Delete", and "Days at Site".

Milestone (5)				Document (13)			
Milestone	Baseline Finish Date	Planned Finish Date	Actual Finish Date	Document Name	Classification	Document Status	Days at Site
Study Country: United States (4)	Max: 12/29/2017	Max: 12/29/2017	Max: 12/27/2017				Avg:
Study Country: United Kingdom (1)	Max:	Max:	Max:				Avg:
All Study Country: (5)	Max: 12/29/2017	Max: 12/29/2017	Max: 12/27/2017				Avg:



# Sharing Reports

- A report is only accessible to the user who creates it unless they choose to Share it
- When a report is shared, the creator can specify users who can edit the report as well as users who can view the report



# Reports

## Exporting Reports

- Reports can be exported as CSV, Excel, or PDF

TMF Completeness by Milestones - All Levels ★

Report Type Milestone with Expected Document

▶ FILTERS (3)

Expand all Collapse all

Milestone (3)	Baseline Finish Date	Planned Finish Date	Actual Finish Date	Expected Document (176)	# Expected
▶ Milestone: IR - First Country Site Initiated (TRB-21-DEC-2017 - United States) (1)					
▶ Milestone: IR - First Study Site Initiated (TRB-21-DEC-2017) (1)					
▶ Milestone: IR - Site Initiated (TRB-21-DEC-2017 - United States - Site-010) (1)					

Refresh Edit

MANAGE

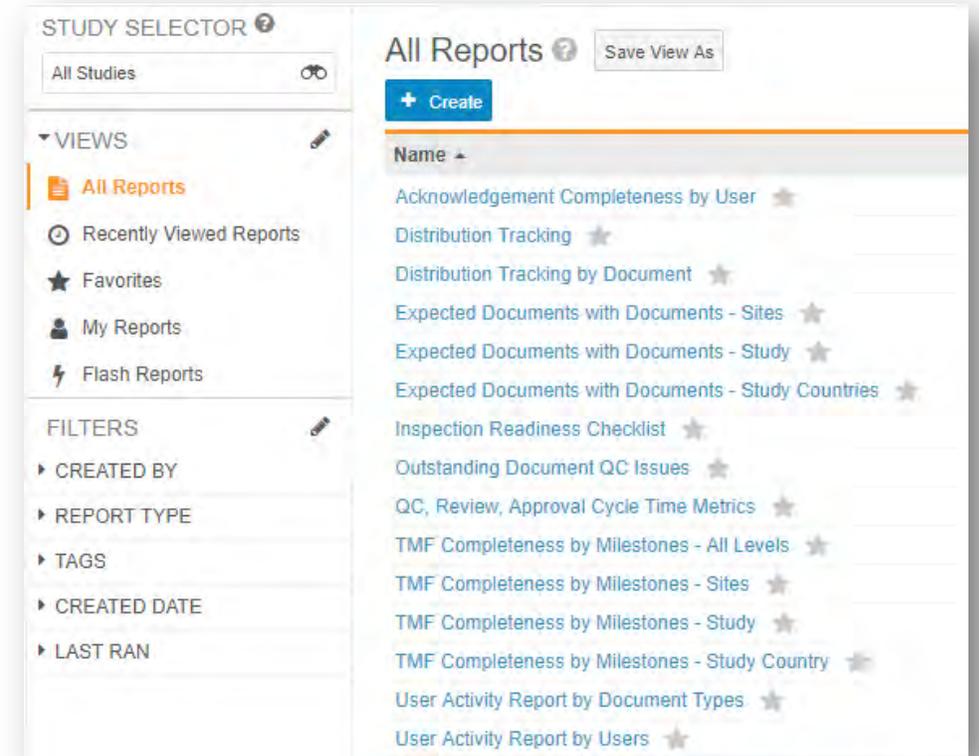
- Share
- Export to CSV
- Export to Excel
- Export to PDF
- Make a Copy
- Delete



# Reports

## Views and Favorites

- From the **Reports** tab, you'll see several views:
  - **All Reports** shows all reports in the vault for which you are an Owner, Viewer, or Editor. All other views are subsets of this view.
  - **Recent Reports** shows the last 20 reports that you have viewed, edited, or created.
  - **My Reports** shows only reports that you have created.
  - **Favorites** shows reports that you have marked as a favorite by clicking the star icon.
  - **Flash Reports** shows all flash reports in the vault for which you are an Owner, Viewer, or Editor
- From the **All Reports** view, you can also use search and filters and edit the column layout to create custom views.
- Click **Save View As** to save this view to your **Views** panel.



# Reports

## Searching, Filtering and Tagging

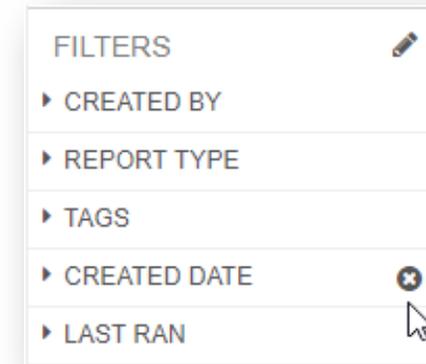
- Search

- Select *Reports* in the main search bar
- Vault searches within the report's name, report type, description, and fields
- Results are displayed in a filtered view in the **Reports** tab



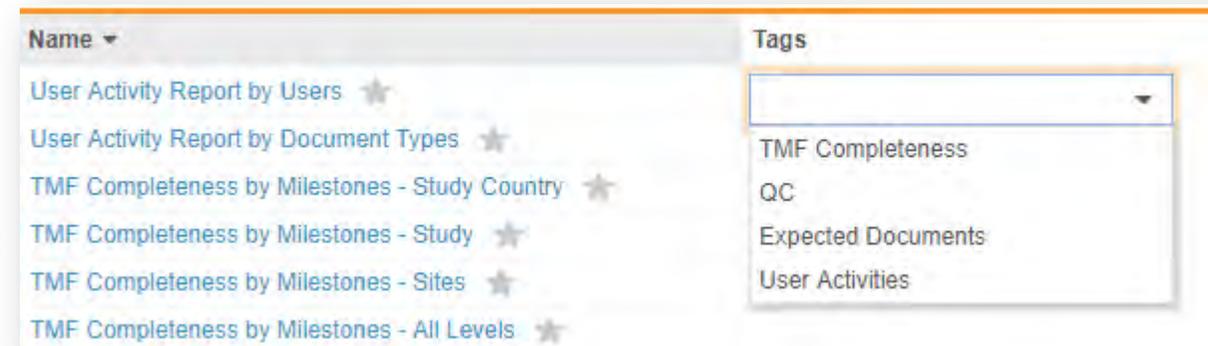
- Filters

- Use the **Filters** option to refine the list of displayed reports in any view or within search results
- Applied filters can be removed by hovering over the filter and clicking the 



- Tags

- Tags can be assigned to a report to make it easier to group, search and filter your reports
- To add tags, click into the **Tags** field for a report and select a tag from the picklist
- The tags picklist is configured by your Admin



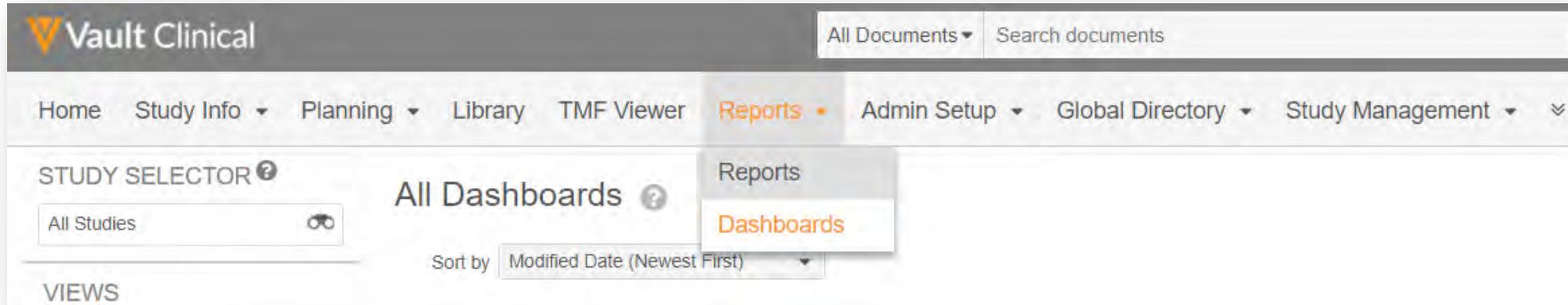


Dashboards

# Dashboards

## Overview

- Dashboards are located through the Reports tab



- Dashboards are visual representations of reports – must have a report before you can create a dashboard
- Can put multiple chart types on a dashboard
  - Gauge
  - Number
  - Column
  - Bar
  - Pie

Resource: <http://vaulthelp2.vod309.com/wordpress/user-help/reporting-user-help/using-dashboards/>



# Dashboards

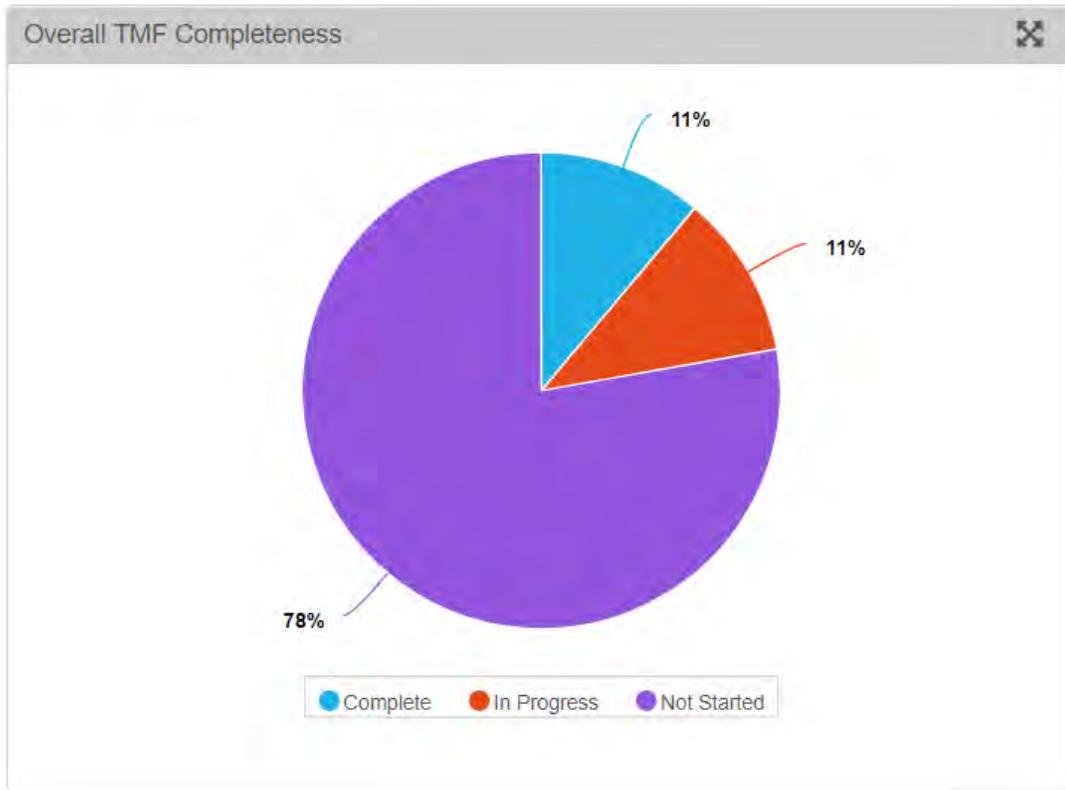
## TMF: Content Processing Metrics

- Average days of documents in the Review workflow until completion
- Average days of documents in the QC workflow until completion
- Average days of documents in the Approval workflow until completion

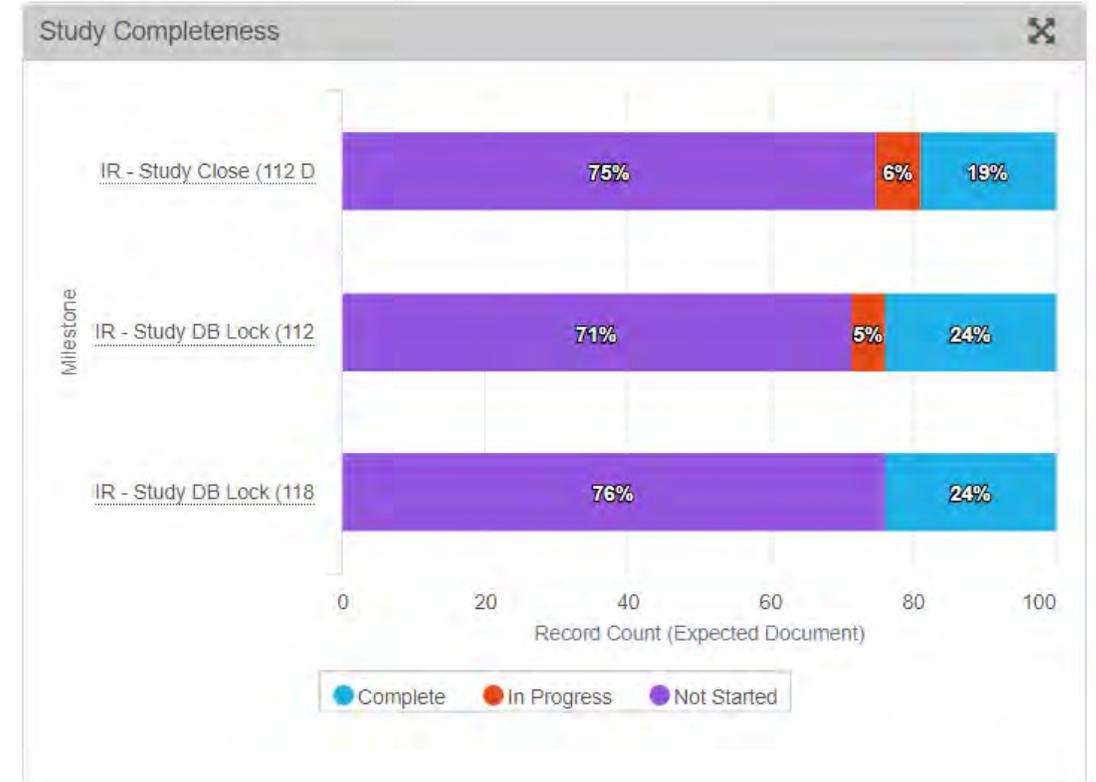


# Dashboards

## TMF Completeness



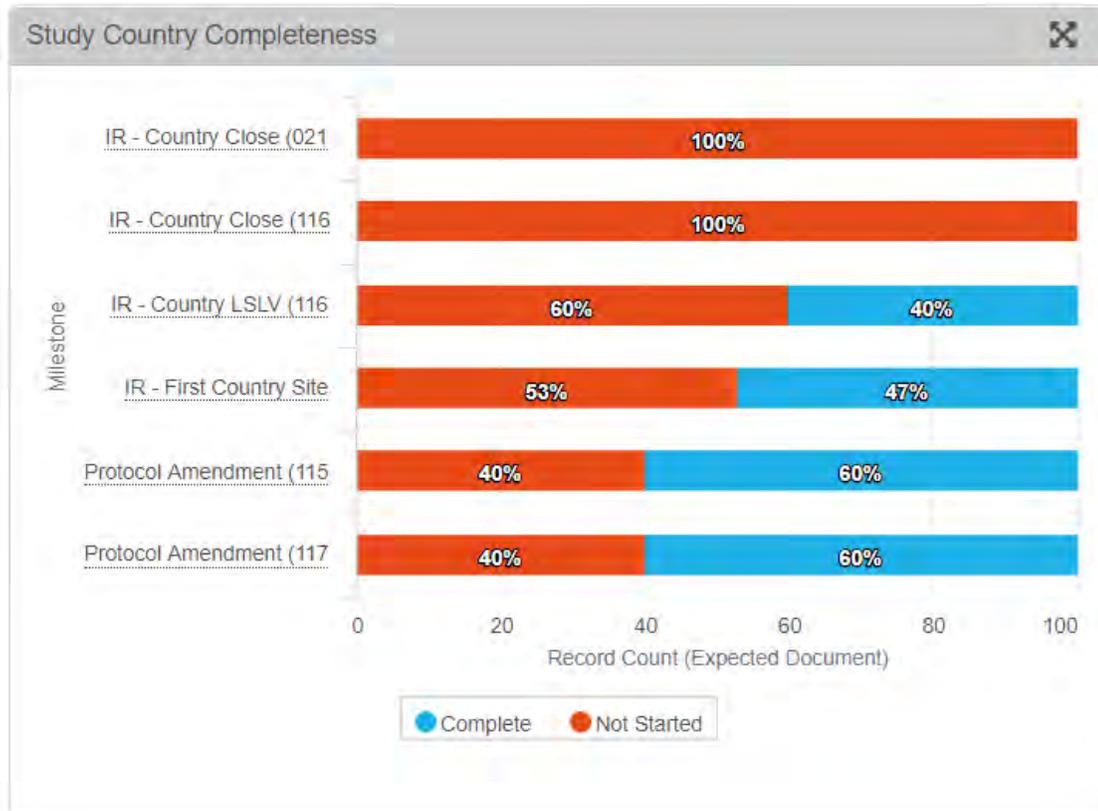
% of document completeness at all levels for the Study selected, categorized by the completeness status



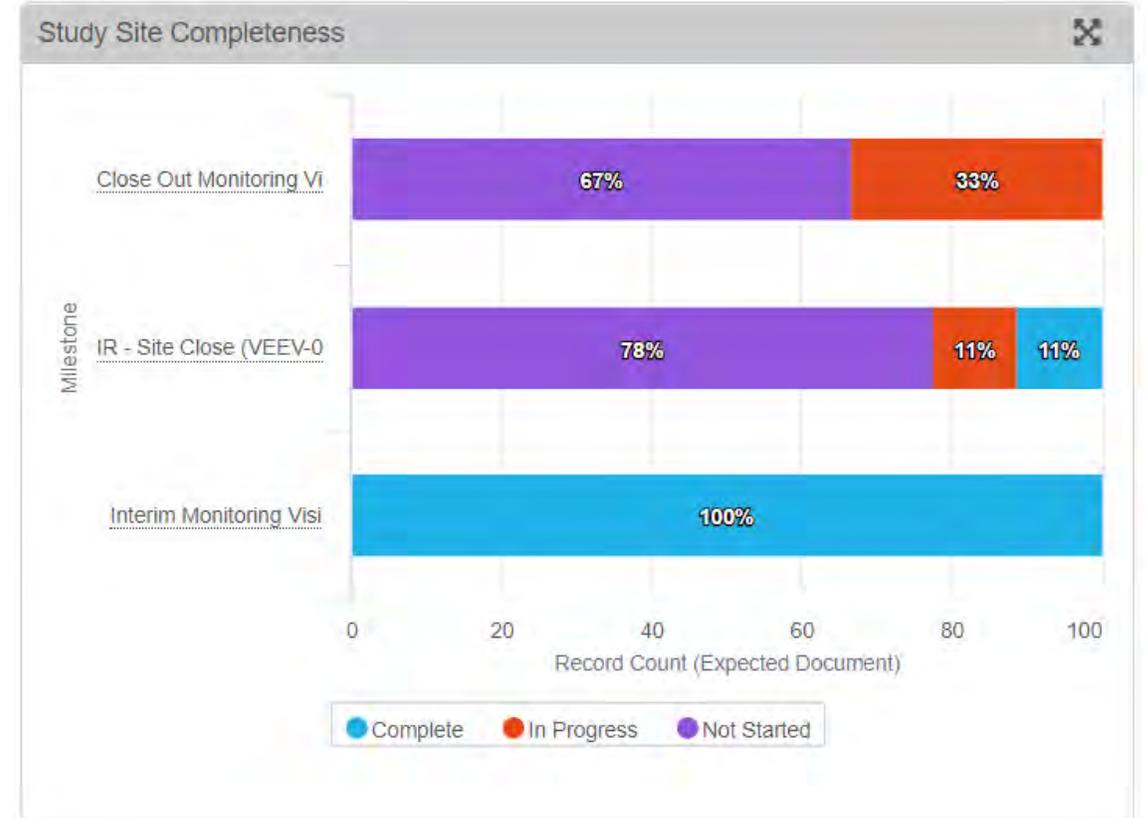
% of document completeness at the Study level for the Study selected, categorized by the completeness status

# Dashboards

## TMF Completeness



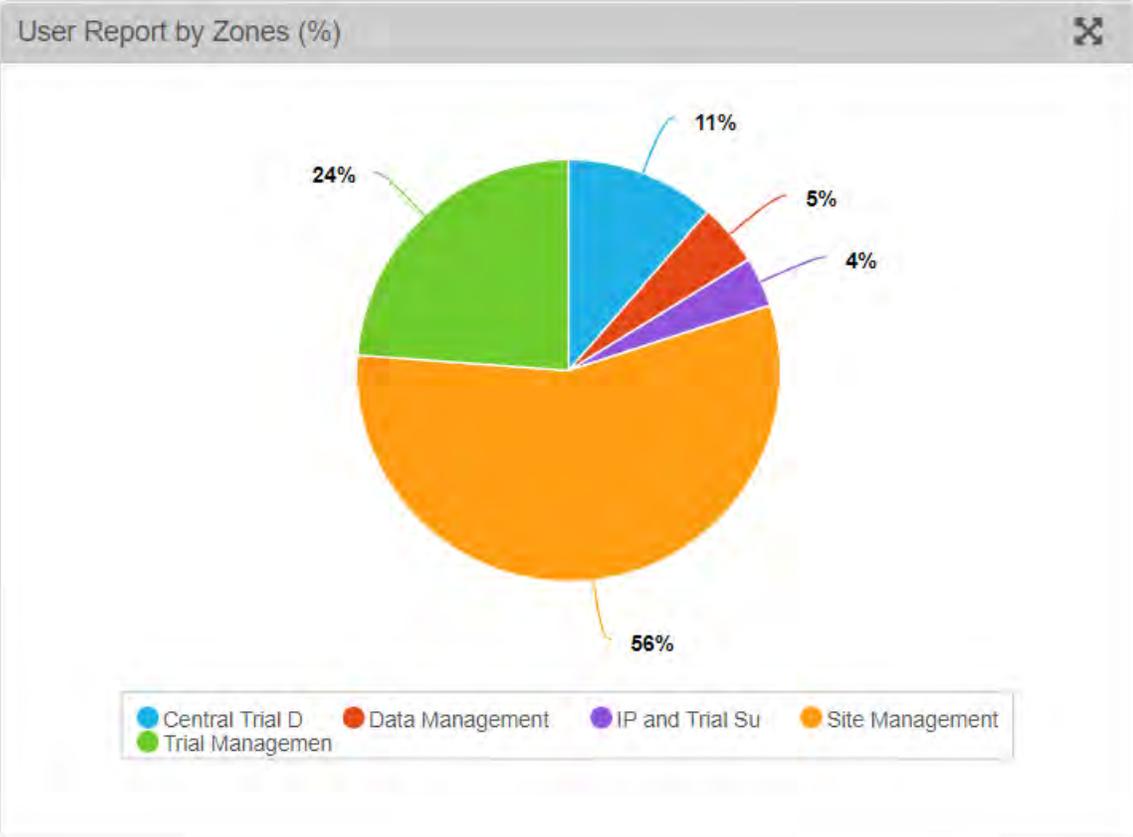
% of document completeness at the Study Country level for the Study selected, categorized by the completeness status



% of document completeness at the Study Site level for the Study selected, categorized by the completeness status

# Dashboards

## TMF: User Activities



% of document types accessed categorized by zones



# of document types accessed categorized by zones





Tips & Tricks

# Best Practices for Reports

- Reports will continue to be refined as your processes and use of the Vault application evolve
- Use controlled values for columns
  - Free text fields are less effective
- Ensure Reports provide Value
  - Should assist the user in finding answers, not an extra burden to hunt for the data
- Consider metrics which have already been defined
- Think about what other users will find important about documents and their statuses
- Think about useful reports and trackers that you currently have or would like to have



# Dashboard Tips

- Use stacked bar/columns for multi-level grouping
- Add target values in chart to compare to goals
- Export chart images to include in PowerPoint
- Use run-time input to create one dashboard that can be used under different context



# Resources

- Vault Help
- [Report Basics Video Tutorial](#)
- [Building Tabular Reports Video Tutorial](#)
- [Building Matrix Reports Video Tutorial](#)
- [Building Dashboards](#)





Questions



Thank you

# Appendix



# TMF Plan Template



## Microsoft Word Document